IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 3 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE OR LIMIT GENERAL-CAUSATION TESTIMONY OF DIONYSIOS K. VERONIKIS, M.D.

Dionysios K. Veronikis, M.D., seeks to offer various opinions regarding the ability of the TVT and Gynemesh PS mesh products to cause the injuries alleged by several plaintiffs in Wave 3 of this litigation.[1] Defendants Ethicon, Inc., Johnson & Johnson, and, if applicable, Ethicon LLC (Ethicon) submit that certain of these opinions are inadmissible under this Court's own rulings, Rules 702 and 403, and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). These opinions include:

- **Opinions relating to what should be included in an IFU**. Dr. Veronikis does not possess the expertise necessary to opine regarding what information should have been included in the IFUs and is therefore not "qualified" as an expert on warnings under Rule 702 and *Daubert*.

[1] Dr. Veronikis offers general-causation opinions only for the TVT and Gynemesh PS products. Yet he is designated as a general-causation expert for several cases—Matthews, Murphy, Reed, Rivers, Toennies, Webb-Henson, Young—that involve products other than TVT or Gynemesh PS. *See* Motion to Exclude or Limit the General Causation Testimony of Dionysios K. Veronikis, M.D., Ex. A at 1-2. Because he does not offer opinions about products other than the TVT and Gynemesh PS, his general-causation opinions do not apply to these cases to the extent harm is alleged to have been caused by those products.

- **Opinion that TVT mesh is not suitable for implantation because it degrades, frays, and loses particles.** Dr. Veronikis's opinion that TVT mesh is defective because it is prone to fraying, falling apart, and degrading within the body is not the product of a reliable methodology because he cannot identify any evidence on which he relied to show that fraying or degradation *causes* clinical problems.

- **Opinion that TVT is defective because the surgical technique used is unsafe.** A surgical technique is not a product. To the extent that Dr. Veronikis criticizes the surgical technique for implanting the TVT, that opinion is inadmissible to prove a design defect.

- **Opinion that all mesh is unsafe for vaginal use**. Dr. Veronikis's opinion that all polypropylene mesh products are unsafe for treating stress urinary incontinence (SUI) is belied by his admission that he uses polypropylene mesh as part of his clinical practice.

- **Opinion that Pronova is a safer alternative to Gynemesh PS**. Dr. Veronikis admits that Pronova, which he believes is a safer alternative mesh design, is not available as an alternative product for prolapse repair. This product therefore cannot serve as either a feasible or safer alternative sufficient to prove a claim for design defect.

- **Opinions that are legal conclusions or relate to Ethicon's motive, knowledge, and intent.** This Court has repeatedly excluded this type of opinion testimony in other cases.

ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard for *Daubert* motions articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Veronikis's warnings opinions should be excluded because he has no "additional expertise" to opine about what should be included in an IFU.

In his reports, Dr. Veronikis is critical of the TVT and Gynemesh PS IFUs and lists various complications and warnings that he claims the IFUs minimize or do not include. He cites "numerous serious safety risks associated with the TVT that have never been included in the TVT IFU," Ex. B, Veronikis TVT Report at 12, including "degradation inside the body" (*id.*) and "'excessive' and 'chronic' foreign body reaction and 'intense' and 'chronic' inflammation" (*id.*). Likewise, as to Gynemesh, he criticizes Ethicon for not passing on its knowledge "that the mesh

material used in construction of Gynemesh PS elicits an 'excessive' and 'chronic' foreign body reaction and 'intense' and 'chronic' inflammation" Ex. C, Veronikis Gynemesh PS Report at 5-6, and "that polyester and even polypropylene tend to alter over time in the body" (*id.* at 6), as well as warnings that Gynemesh PS is "stiff," "inflexible," "too strong and not designed for the pelvic floor" (*id.* at 7), and carries the risk of "nerve entrapment, nerve tethering, and nerve severing" (*id.* at 12).

Dr. Veronikis, however, is not qualified to offer these or any other opinions about what should be included in an IFU. Although a urogynecologist like Dr. Veronikis may testify "about specific risks of implanting mesh and whether those risks appeared on the relevant IFU," that "same expert must possess *additional expertise* to offer expert testimony about what information *should or should not be included in an IFU*." *In re Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *4 (S.D.W. Va. Aug. 26, 2016) (emphasis added) (excluding Dr. Blavias's warnings opinions because he "is not an expert in the development of warning labels and thus is not qualified to offer expert testimony about warnings.")

By his own admission, Dr. Veronikis does not possess the "additional expertise" necessary for a urogynecologist to be able to opine on what information should be included in an IFU. He has not drafted—or consulted on drafting—instructions for use for implantable medical devices, generally, much less mesh slings, specifically. Although he testified that he *has* written IFUs in the past, they have been for "instruments of his own design," including "a vaginal dilator for women that have a shortened vagina" and "an instrument to do pelvic surgery, sacrospinous colpopexy." Ex. D, Veronikis 4/30/16 Dep. Tr. 163:18-164:8. Those experiences are irrelevant to drafting IFUs for an actual medical *device*. Moreover, Dr. Veronikis admitted that he did not

even decide himself what should go into the IFUs: "They gave me a handout on what it should include, and I wrote it." *Id.* 164:11-14.

In short, Dr. Veronikis does not possess the "additional expertise" necessary that would qualify him to opine on what should be included in an IFU for an implantable medical device. Consequently, his warnings opinions should be excluded under Rule 702 and *Daubert*.

II. Dr. Veronikis's opinion that TVT is not suitable for implantation because it degrades, frays, and loses particles is not based on a reliable methodology.

Dr. Veronikis's defective-design opinions are anchored in his belief that TVT mesh frays, degrades, and loses particles after implantation, which render it unsuitable for use in treating SUI. Ex. B, Veronikis TVT Report at 5, 9-10. Although Ethicon acknowledges that this Court declined to exclude Dr. Veronikis's fraying and degradation opinions in its Wave 1 ruling, *In re: Ethicon Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02327, 2016 WL 4582232, at *3 (S.D.W. Va. Sept. 1, 2016), that holding was limited to a finding that "Dr. Veronikis's reliance on Ethicon's internal documents" does not, in itself, render his opinions unreliable. *See id.*

But even if Dr. Veronikis may rely on internal Ethicon corporate documents as a basis to opine that fraying and degradation *occur*, reliance on those documents is not a reliable methodology for supporting his opinion that fraying and degradation *cause clinical problems*. Indeed, Dr. Veronikis himself admitted that he has not seen evidence—either internal corporate documents or scientific studies—to support his opinion that TVT is defective because fraying and degradation lead to clinical problems:

> Q. Have you read any study that the TVT® mesh falling apart, pieces coming off it, have been a clinical problem for anyone?
>
> A. I've read in the Ethicon documents that people complained that it was fraying.

> Q. Have you read any published scientific literature where fraying and the TVT® mesh falling apart was recognized to be a problem?
>
> A. Not yet.

Ex. D, Veronikis 4/30/16 Dep. Tr. 72:20-73:7. By his own admission then, he has no support for his opinions that degradation, fraying, or particle loss cause clinical problems, making the TVT unsuitable for implantation. These opinions should be excluded.

Further, although Dr. Veronikis claimed during his deposition to rely on the Clavé study, which he claims "says that degradation of TVT® polypropylene produces clinical problems" Ex. D, Veronikis 4/30/16 Dep. Tr. 98:4-8, he admits that he did not cite this study *or* discuss it as the basis for any opinion expressed in the body of his report (*id*. at 294:22-295:13). Even so, the footnote reference is merely mentioned as part of Dr. Veronikis's narrative history of Ethicon internal company documents as to what Ethicon "knew." Ex. B, Veronikis TVT Report at 12 n.29; Ex. C, Veronikis Gynemesh PS Report at 6 n.3. It is cited for nothing more. Without any support for his opinion, it is merely *ipse dixit* and excludable on that basis. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D.W. Va. 2013) (excluding general-causation testimony offered by expert as inadmissible *ipse dixit* where the expert failed to identify any supporting basis for the opinion, including scientific literature).

III. Dr. Veronikis's surgical-technique opinion should be excluded as irrelevant.

Although not included in his Rule 26 report, Dr. Veronikis testified that aspects of the *surgical technique* for TVT render it "unsafe" and unsuitable for use. Ex. D, Veronikis 4/30/16 Dep. Tr. 21:10-24:3. Specifically, he emphasized that his criticism of the technique is inseparable from his criticism of the TVT mesh design: "I have criticism of both. I don't know which one would be more because they're sort of together. You really can't isolate the one from the other." *Id.* at 27:16-19. This new, previously undisclosed opinion should be excluded for Dr.

Veronikis's failure to comply with Rule 26 (*see In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 644 (new opinion not discussed in a Rule 26 expert report or supplemental report excluded)), but is independently inadmissible because it is irrelevant to Plaintiffs' design-defect claims.

Ethicon acknowledges that this Court has reserved ruling on whether Dr. Veronikis's "surgical technique" opinion is relevant to a claim for design defect, preferring instead to address the relevancy of this opinion in the individual cases. *In re Ethicon*, 2016 WL 4582232 at *3 ("The relevance of a matter like this is best assessed in context during trial. . . ."). Nevertheless, Ethicon submits that criticism of surgical technique cannot support a claim that an implantable medical device is defectively designed as a matter of law, and therefore is not relevant to *any* of these individual cases. *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (rejecting plaintiff's theory that defendant's spinal-fixation device was defective because there were alternative spinal-fusion procedures available that did not use spinal-fixation devices); *Bogle v. Sofamor Danek Grp., Inc.*, No. 95-8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999) (emphasizing that the expert's "testimony fails to identify any particular defect *with the product*. He testified that the design of the screw made it difficult to utilize, that only the most skilled surgeons could implant it with any degree of success, that if he were designing a pedicle screw he would design it differently . . . . The Court is not persuaded that such testimony identifies a defect in the product, rather, at the most it identifies that it is a product reserved to a top-rate surgeon" (emphasis added)); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999) (granting summary judgment on design-defect claim where expert focused on surgical technique and non-instrumental spinal repair, not a defect in the product itself); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (granting summary

judgment to defendant because "[t]he fact that an alternative method of surgical hernia repair was potentially available does not support Plaintiff's design defect claim").

To the extent that Dr. Veronikis's design-defect opinion is premised on criticism of the TVT surgical technique, that opinion is not relevant because a surgical technique is not a product for purposes of proving a claim for design defect.

IV. Dr. Veronikis's opinion that polypropylene mesh is defective when used transvaginally lacks intellectual rigor because it is inconsistent with his clinical practice and is therefore unreliable.

Dr. Veronikis proposes to testify that the "benefits of the TVT are outweighed by the serious complications associated with the device" and that, consequently, the product "is not suitable for its intended application." Ex. B, Veronikis TVT Report at 5, 8. His deposition testimony, however, confirms that Dr. Veronikis's opinions are not limited to just TVT, but that he views *all* polypropylene mesh slings as inherently unsafe for treatment of SUI:

> Q. So is it fair to say that all of the meshes that are on the market today, you consider all of them for SUI surgery to be unsafe?
>
> A. At this point in time with everything I've reviewed and everything I've learned, they are not safe.
>
> Q. Okay. None of them?
>
> A. None of them.

Ex. D, Veronikis 4/30/16 Dep. Tr. 144:10-18.

But Dr. Veronikis's sweeping condemnation of polypropylene mesh in this litigation cannot be squared with his ongoing clinical practice. He freely concedes that he still uses polypropylene mesh slings today. Specifically, he has been using a polypropylene sling manufactured by Caldera, called "Desara," since 2010 to treat patients with SUI. *Id.* at 27:20-28:10. He should not be permitted to offer the litigation-driven opinion that use of polypropylene

mesh is unsafe when that opinion is contrary to what he advocates for the patients he treats in his clinical practice—*i.e.*, that the use of polypropylene mesh is safe.

Ethicon acknowledges that this Court has found this inconsistency between an expert's "transvaginal-mesh-is-unsafe" opinion and the expert's "transvaginal-mesh-is-safe" practice is not a basis for exclusion with respect to the safety opinions offered by another expert. *See In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, No. MDL 2327, 2016 WL 4536456, at *3 (S.D.W. Va. Aug. 30, 2016) (denying motion to exclude Dr. Ostergard's transvaginal-mesh-is-unsafe opinion even though it is inconsistent with his transvaginal-mesh-is-safe practice). But the unequal approach Dr. Veronikis employs—one for rendering opinions for litigation and the other for treating his patients—underscores the lack of intellectual rigor he employs in formulating opinions, rendering his transvaginal-mesh-is-unsafe opinion unreliable.

Indeed, as *Daubert* and this Court have made clear, an expert must "'employ[] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field . . . .'" *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 675 (S.D.W. Va. 2014) (quoting *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 203 (4th Cir. 2001)); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (instructing that an expert must employ in the courtroom "the same level of intellectual rigor that characterizes the practice of an expert" in the expert's field). When the expert employs one standard for a courtroom and another standard for his everyday practice, the standard he crafted just for the courtroom is excludable under *Daubert*. *See Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *10 (S.D.W. Va. May 6, 2015) (excluding Dr. Blavias's safety opinion because he "'phrase[s] [his] words differently in the peer-reviewed literature than [he] do[es] in the legal literature because it's two different sets of rules'").

This is precisely what Dr. Veronikis does here. As such, Dr. Veronikis's continued use of a transvaginal polypropylene mesh product in his clinical practice shows that his opinion that *all* polypropylene mesh is unsafe for SUI surgery lacks the intellectual rigor required by *Daubert* and its progeny, and is instead an opinion that has been crafted solely for this litigation. It should be excluded.

V. Pronova—a different product—is not a *feasible* or *safer* alternative design because, as Dr. Veronikis concedes, it is not available for and has not been studied for prolapse repair, making his alternatives opinion irrelevant.

During his deposition, Dr. Veronikis opined for the first time that there is an alternative mesh design, called Pronova,[2] which he believes would be safe for use in prolapse repair. Ex. D, Veronikis 4/30/16 Dep. Tr. 238:1-239:7. This is a new opinion, which was never expressed in his Rule 26 expert reports, and should be excluded for that reason alone. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 644. Indeed, while Ethicon acknowledges that this Court has previously reserved ruling on Dr. Veronikis's "alternatives" opinion, *see In re Ethicon*, 2016 WL 4582232 at *2-3, Ethicon submits that Dr. Veronikis's failure to include his opinion about Pronova in his report calls for its exclusion as a matter of law in these cases.

And even though the Court reserved ruling on Dr. Veronikis's alternatives opinion, it did so because it understood the opinion to be based on experience. *Id*. Ethicon submits that Dr. Veronikis's Pronova opinion is not so. By his own admission, Dr. Veronikis bases this opinion on nothing more than internal company documents he saw during his preparation for this case. Ex. D, Veronikis 4/30/16 Dep. Tr. 238:1-4, 239:21-240:12. He did not base this opinion on his

[2] Pronova is a suture "indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures." *See* http://www.ethicon.com/healthcare-professionals/products/wound-closure/non-absorbable-sutures/pronova-poly-hexafluoropropylene-vdf. It was cleared by the FDA in 2000 for that use. *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K001625.

experience with this product. *Id*. And he admits there has been no peer-reviewed literature to determine whether Pronova can be used for prolapse repair. *Id.* at 240:13-16.

But more importantly, Dr. Veronikis's new opinion regarding Pronova has no bearing on whether it is a *feasible* or *safer* alternative design for prolapse repair because he agreed it is not available for use in prolapse repair. When asked whether "there's any safe alternative for the use of mesh . . . for prolapse" during his deposition, Dr. Veronikis testified "[n]ot the current mesh that we have." *Id.* at 237:13-20. He further conceded that Pronova has not even been used for prolapse repair in studies. *Id.* at 239:1-3.

Nor has it been cleared for use as a mesh sling. Instead, as noted, Pronova is a suture indicated for use in general soft tissue approximation or ligation, including cardiovascular, ophthalmic and neurological surgery[3] and cleared by the FDA for those uses.[4] Thus, it cannot be a "feasible" alternative. *See Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 572 (E.D. Pa. 2011) (applying Pennsylvania law and finding "[t]here exists no FDA-approved alternative form of ibuprofen, meaning there is no available alternative design of the drug for defendants to adopt"); *see also In re Alloderm Litig.*, Nos. MID-L-5972-11, MID-L-507-12, MID-L-1469-12, 2015 WL 5022618, at *12 (N.J. Super. Aug. 14, 2015) (noting that an alternative product must be commercially available, which requires FDA action).

And Pronova is not evidence of a *safer* alternative design because it is an entirely different product. *See Hosford v. BRK Brands, Inc.*, No. 1140899, 2016 WL 4417256, at *5-6 (Ala. Aug. 19, 2016) (finding, as a matter of law, that a proposed alternative product, even one

[3] *See* http://www.ethicon.com/healthcare-professionals/products/wound-closure/non-absorbable-sutures/pronova-poly-hexafluoropropylene-vdf. (last accessed Sept. 13, 2016)

[4] *See* http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K001625. (last accessed Sept. 13, 2016)

with essentially the same purpose, is not a safer alternative design for an entirely different product; "rather, it is a design for a different product altogether") (relying on *Brockert v. Wyeth Pharm., Inc.*, 287 S.W.3d 760 (Tex. App. Ct. 2009) and *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379 (Tex. 1995)).

At bottom, Dr. Veronikis's Pronova opinion should be excluded. Aside from being a new opinion offered in violation of Rule 26, it is also irrelevant because it is neither feasible nor safer.

VI. Dr. Veronikis's opinions expressing legal conclusions, what Ethicon knew, or its motives and intent, should be precluded.

A. Impermissible legal conclusions should be excluded.

This Court has made clear on numerous occasions that drawing legal conclusions is within the province of the jury, not the subject of expert testimony. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 629; *see also Eghnayem*, 57 F. Supp. 3d at 691 ("In the Fourth Circuit, 'opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.'" (quoting *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006)).

Despite this well-established rule of law, Dr. Veronikis seeks to offer several legal conclusions, including, but not limited to:

- The TVT mesh "is not suitable for its intended application" (Ex. B, Veronikis TVT Report at 5);
- "Ethicon failed to adequately describe, inform or explain to physicians how to properly 'tension' the TVT" (*id.*);
- Ethicon's "Instructions for Use ("IFU") are inadequate based on Ethicon['s] failure to include warnings about the adverse reactions and risks . . . ." (*id.*);
- TVT "is defectively designed" because "[a]ny benefits that Ethicon believes are attributable to the TVT are outweighed by the risks of the device" (*id.* at 7-8);
- "Ethicon failed to adequately warn physicians and patients about known problems with the TVT" (*id.* at 10);

- "Ethicon failed to warn about the risk of stiffness and resulting pain associated with the laser cut TVT mesh" (*id*. at 14);
- "Ethicon failed to warn about the difficulty of removing the TVT mesh in its entirety once it is implanted" (*id*. at 14);
- "Ethicon failed to warn physicians and patients about the risks associated with the Gynemesh PS . . . ." (Ex. C, Veronikis Gynemesh PS Report at 10);
- "Ethicon failed to adequately convey any warning to doctors regarding . . . adverse study results" (*id*. at 15);
- "Gynemesh PS should not have been considered reasonably safe for repair of pelvic organ prolapse" (*id*.); and
- "[T]he risks of Gynemesh PS for transvaginal pelvic organ prolapse repair far outweighed any claimed benefits, and the implantation of this product resulted in unacceptable rates of" mesh-related injuries (*id*. at 23).

Consistent with this Court's earlier rulings, Dr. Veronikis should be precluded from offering these legal conclusions.

B. Corporate-knowledge/motive/intent opinions should be excluded.

Dr. Veronikis relies on internal company documents to offer opinions about what Ethicon knew and what it intended. Ex. B, Veronikis TVT Report at 5; Ex. C, Veronikis Gynemesh PS Report at 9. As explained, this Court has repeatedly excluded testimony based on "Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics" because they "are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Lewis* v. Ethicon, Inc., No. 2:12-cv-4301, 2014 WL 186872, at *6 (S.D.W. Va. Jan. 15, 2014); *see also Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *3-4 (S.D.W. Va. Feb 7, 2015); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691,703 (S.D.W. Va. July 8, 2014). Consistent with those rulings, Dr. Veronikis's corporate-knowledge/motive/intent opinions should be excluded in their entirety, including (but not limited to) the following opinions:

- Opinion that Ethicon "knew that the . . . mesh (Prolene) was not appropriate" and that certain risks "were known" to Ethicon" (Ex. B, Veronikis TVT Report at 5);

- Opinion that Ethicon's IFU was "intentionally misleading" because "Ethicon carried out no tests or studies" to back up statements made within the IFU (Ex. C, Veronikis Gynemesh PS Report at 9);

- Opinion that Ethicon would be "needlessly endangering" its patients if it did not warn in the IFU of "a portion of the population not listed which would be subject to additional risks" (*id.* at 16); and

- Opinion that "Ethicon's documents reflect an intent to 'differentiate'" study results that were purportedly not supportive of "the clinical safety of the Prolift kit" (*id.* at 21).

CONCLUSION

For these reasons, Ethicon asks this Court to grant its Motion to Exclude or Limit the General-Causation Testimony of Dionysios K. Veronikis, M.D.

Respectfully submitted,

ETHICON, INC., JOHNSON & JOHNSON, AND ETHICON LLC

/s/ Rita A. Maimbourg
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
THOMAS COMBS & SPANN PLLC
300 Summers St.
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
Tel: 304.414.1807
dthomas@tcspllc.com

/s/ Christy D. Jones
Christy D. Jones
BUTLER SNOW LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
Tel: 601.985.4523
christy.jones@butlersnow.com

CERTIFICATE OF SERVICE

I certify that on September 19, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Rita A. Maimbourg
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com